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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/723,207 | 11/24/2003 | Chang Yi Wang | 1151-4153US2 | 8598 |

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| EXAMINER | |
|---|---|
| ROONEY, NORA MAUREEN | |
| ART UNIT | PAPER NUMBER |
| 1644 | |

DATE MAILED: 08/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/723,207 | WANG ET AL. | |
| | Examiner | Art Unit | |
| | Nora M. Rooney | 1644 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *24 November 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-28* are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

1. It appears that claim 25 should depend from claim 24.

### *Election/Restrictions*

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-3, drawn to an IgE-CH3 domain antigen peptide, classified in class 424, subclass 185.1 and class 530, subclass 391.1.

II. Claims 5, 7-13, 15-18 and 24, drawn to a peptide conjugate represented by the formula: **$(A)_n$-(IgE-CH3 domain antigen)-$(B)_0$-$(Th)_m$-X**, classified in class 424, subclass 185.1 and class 530, subclass 391.1.

III. Claims 5, 7-13, 15-18 and 24, drawn to a peptide conjugate represented by the formula: **$(A)_n$-$(Th)_m$-$(B)_0$-(IgE-CH3 domain antigen)-X**, classified in class 424, subclass 185.1 and class 530, subclass 391.1.

IV. Claims 6,-13, 15-18 and 24, drawn to a peptide conjugate represented by the formula: **(IgE-CH3 domain antigen)-$(B)_0$-$(Th)_m$-$(A)_n$-X**, classified in class 424, subclass 185.1 and class 530, subclass 391.1.

V. Claims 6-13, 15-18 and 24, drawn to a peptide conjugate represented by the formula: **$(Th)_m$-$(B)_0$-(IgE-CH3 domain antigen)-$(A)_n$-X**, classified in class 424, subclass 185.1 and class 530, subclass 391.1.

VI. Claims 19 and 20, drawn to a peptide conjugate with a carrier protein, classified in class 424, subclass 185.1 and class 530, subclass 391.1.

VII. Claims 14, 21 and 24-25, drawn to a peptide and a pharmaceutical composition comprising an immunologically effective amount of a peptide, classified in class 530, subclass 350.

VIII. Claims 22 and 23, drawn to a polymer comprising a peptide, classified in class 530, subclass 402.

IX. Claim 26, drawn to a method of inducing anti-IgE antibody production in a mammal using a polymer, classified in class 530, subclass 402.

X. Claim 27, drawn to a method for inducing anti IgE antibody production in a mammal using a peptide, classified in class 530, subclass 39.1.

XI. Claim 27, drawn to a method for inducing anti IgE antibody production in a mammal using a peptide conjugate, classified in class 530, subclass 39.1.

XII Claim 28, drawn to a nucleic acid, classified in class 536, subclass 23.1.

3. Claim 4 links inventions II-XI. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim, claim 4. Upon the allowance of the linking claim, the restriction requirement as to the linked inventions shall be withdrawn and any claims depending from or otherwise including all the limitations of the allowable linking claim will be entitled to examination in the instant application. Applicants are advised that if any such claims depending from or including all the limitations of the allowable linking claim are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the

provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

4. Groups I- VIII and XII are different products. The peptide of Group I, the polypeptide conjugates of Groups II-VI, the peptide of Group VII, the polymers of Groups VIII and the nucleic acids of Groups XII all differ with respect to their structures and physicochemical properties; therefore each product is patentably distinct.

Inventions I and II-VII are related as mutually exclusive species in an intermediate-final product relationship. Distinctness is proven for claims in this relationship if the intermediate product is useful to make other than the final product, and the species are patentably distinct (MPEP § 806.05(j)). In the instant case, the intermediate product is deemed to be useful for making monoclonal antibodies and the inventions are deemed patentably distinct because there is nothing on this record to show them to be obvious variants.

5. Groups IX-XI are different methods. The method of inducing anti-IgE antibody production in a mammal with a polymer of Group IX is different from the method of inducing anti-IgE antibody production in a mammal with a peptide or peptide conjugate with respect to ingredients, method steps, and endpoints; therefore, each method is patentably distinct.

6. Groups I-VIII and X and Groups IX -IX are related as product and process of using. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). The peptide and peptide conjugates of Groups I-V and the polymer containing peptide conjugates of Group VII can be used for affinity purification. Also, the

nucleic acid of Group XII can be also used for in situ hybridization. Therefore, the product and process of using claims are distinct.

7. These inventions are distinct for the reasons given above. In addition, they have acquired a separate status in the art as shown by different classification and/or recognized divergent subject matter. Further, even though in some cases the classification is shared, a different field of search would be required based upon the structurally distinct products recited and the various methods of use comprising distinct method steps. Therefore restriction for examination purposes as indicated is proper. Further, a prior art search also requires a literature search. It is an undue burden for the examiner to search more than one invention.

*Species Election*

8. Irrespective of whichever group applicant may elect, applicant is further required under 35 U.S.C 121: (1) to elect a single disclosed species to which claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

A. If Group I or VI is elected, applicant is required to elect a single IgE-CH3 domain antigen peptide of a.) SEQ ID NO:5, b.) SEQ ID NO:6, c.) SEQ ID NO: 7 or d.) SEQ ID NO: 84.

The peptide species differ with respect to their structures, expression, modes of action and physicochemical properties; therefore each product is patentably distinct.

B. If one of Groups II-V is elected, applicant is required to elect a single specific peptide conjugate wherein:

1.) a single specific IgE-CH3 domain sequence is designated such as the one in claims 8-9;and

2.) a single specific Th sequence is designated such as the one in claims 7, 10 and 11-13; and

3.) a single specific B is designated.

The peptide species differ with respect to their structures, expression, modes of action and physicochemical properties; therefore each product is patentably distinct.

C. If Group VII is elected, applicant is required to elect a single specific peptide such as the one in claim 14 or 21 such as wherein the sequence is:

**1.)** SEQ ID NO:14; **2.)** SEQ ID NO:15; **3.)** SEQ ID NO:17; **4.)** SEQ ID NO:18; **5.)** SEQ ID NO: 19; **6.)** SEQ ID NO:20; **7.)** SEQ ID NO:21; **8.)** SEQ ID NO: 22; **9.)** SEQ ID NO:23; **10.)** SEQ ID NO:24; **11.)** SEQ ID NO:25; **12.)** SEQ ID NO:26; **13.)** SEQ ID NO: 27; **14.)** SEQ ID NO:85; **15.)** SEQ ID NO:87; **16.)** SEQ ID NO: 88; **17.)** SEQ ID NO:90; or **18.)** SEQ ID NO:91.

The peptide species differ with respect to their structures, expression, modes of action and physicochemical properties; therefore each product is patentably distinct.

D. If one of Groups VIII-X is elected, applicant is required to elect:

1.) a single peptide conjugate wherein:

a.) a single specific IgE-CH3 domain sequence is designated such as the one in claims 8-9; and

b.) a single specific Th sequence is designated such as the one in claims 7, 10 and 11-13; and

c.) a single specific B is designated;

**OR**

2.) a single specific peptide such as the one in claim 14 or 21 such as wherein the sequence is:

**1.)** SEQ ID NO:14; **2.)** SEQ ID NO:15; **3.)** SEQ ID NO:17; **4.)** SEQ ID NO:18; **5.)** SEQ ID NO: 19; **6.)** SEQ ID NO:20; **7.)** SEQ ID NO:21; **8.)** SEQ ID NO: 22; **9.)** SEQ ID NO:23; **10.)** SEQ ID NO:24; **11.)** SEQ ID NO:25; **12.)** SEQ ID NO:26; **13.)** SEQ ID NO: 27; **14.)** SEQ ID NO:85; **15.)** SEQ ID NO:87; **16.)** SEQ ID NO: 88; **17.)** SEQ ID NO:90; or **18.)** SEQ ID NO:91.

The peptide species differ with respect to their structures, expression, modes of action and physicochemical properties; therefore each product is patentably distinct.

E. If Group X is elected, applicant is required to elect a nucleic acid sequence encoding a single peptide such as the one recited in claims 1-6 which discloses a specific SEQ ID NO.

The nucleic acid species encoding a single polypeptide differs with respect to structure, and physicochemical properties; therefore each product is patentably distinct.

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

9. Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.\

10. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

11. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

12. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nora M. Rooney whose telephone number is (571) 272-9937. The examiner can normally be reached Monday through Friday from 8:30 am to 5:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

August 7, 2006

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Patent Examiner

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~~PATENT~~ EXAMINER
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